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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,618	02/15/2002	Alexander J. Feigl	AFEI:002US 10006443 *	2880

7590

12/29/2004

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/077,618

Applicant(s)

FEIGL, ALEXANDER J.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/15/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11,31-41 and 64-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11,31-41 and 64-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-11, 31-41, 64-66, and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,190,396 to Whitin et al. Regarding Claims 1 and 64, and with reference to Figure 9, Whitin discloses a device including a body (20). Body (20) has a lumen (80) extending from a first lumen opening on the lateral side of the tube to a second lumen opening on the proximal end of the body. The lumen is adapted to receive a needle (70) and a suture [Column 9, lines 30-34]. The suture (inside and outside of the lumen) is visible in Figure 9.

Whitin's body (20) also has a first needle guide channel (80), which extends from a first needle guide channel opening on the lateral side of the tube to a second needle guide channel opening on the proximal end of the body. Examiner emphasized that Whitin discloses multiple lumens/channels, each having a separate proximal opening as is apparent from the cross sectional view of Figure 9.

Whitin's configuration is just as capable of performing the intended use as Applicant's invention. Whitin does not disclose such an intended use, but the user

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could arrange the needle and suture in the configuration mentioned by Applicant and pull the suture, as intended by the Applicant.

2. Regarding Claims 2, 8, 9, 32, 38, 39, and 65, each of Whitin's needle guide channels is shaped like an arc [apparent from Figure 9].
3. Regarding Claims 3-5 and 33-35, Whitin's device (10) has a handle coupled to body (20). The handle is especially well shown in Figures 1 and 2, and takes the form of a handle with a trigger, as in a gun. This handle is coupled to the body (20) through the various mechanisms of the device, as obvious in Figure 1. These mechanisms can be referred to as connector pieces. For example, one of the connector pieces are push rods (156), which must be bendable, because they "traverse the curved channel 80" [Column 9, lines 35-41].
4. Regarding Claims 6 and 36, Whitin's body is tapered, towards the distal end, as shown in Figure 9.
5. Regarding Claims 7 and 37, Whitin discloses multiple (eight, specifically) additional needle guide channels, each extending from its own first needle guide channel opening formed in the body (20) to its own second needle guide channel opening formed in the body. In Figure 9, although only one needle guide channel and one lumen are shown, this is because this view is a cross sectional view. Whitin discloses that either the pusher with push rods (156) as shown in Figure 12 or the pusher of Figure 11 may be used to push the needles/sutures through the needle guide channels of Figure 9 [Column 9, lines 32-41]. *This implies that there are as many channels to receive the needles/pushers, as there are needles/pushers.*

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6. Regarding Claims 10, 11, 40, and 41, because the pushers appear to be equidistant and arranged circumferentially [see Fig. 12], the needle guide channels (80) necessarily will also be equidistant and arranged circumferentially.
7. Regarding Claim 31, Whitin's body (20) has a first needle guide channel (80), which extends from a *first needle guide channel opening* on the lateral side of the tube to a second needle guide channel opening on the proximal end of the body. Thus, Whitin has anticipated a claim to a body with only one needle guide channel.
8. Further regarding Claims 31 and 37, Whitin's apparatus is *capable of performing such an intended use*. As shown in Attachment #1, were one to back load the needle into the position as shown and pull on the suture forward (direction #1), then the needle will advance out of the body backwards (direction #2). Although Whitin does not specifically disclose this use of his device, his device is capable of such a use. His device is certainly "*configured*" *in such a way to allow this use of his invention*.
9. Regarding Claim 66, Whitin's body (20) has a proximal extension, which can be used to grip the body (20) [the extension appears rectangular in Fig. 9].
10. Regarding Claim 69, the distal portion of Whitin's body is tapered.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 64-69 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S.

Patent No. 6,206,893 B1 to Klein et al. Regarding Claims 64, 65, and 69, Klein

discloses a medical device (10) having all of the features claimed by Applicant, as shown in Fig. 2: body (12) includes both the cylindrical part with lumen (24) and the tapered distal part containing arcuate needle guide channel (36). Although a thin neck part separates the aforementioned parts of the body, *they are unitary*, as denoted by the continuous and identical hatch marks in the cross-sectional view of Fig. 2. A flexible needle (42) is attached to suture (62) and is capable of being “backloaded” into needle guide channel (36) because of its flexibility.

12. Regarding Claims 66-68, handle (114) is coupled to the body and is also attached to connector piece (110). Connector piece (110) is bendable in that it is bendable (i.e. rotatable) relative to the body (12) and the handle (114) to be in a variety of positions.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,845,645 to Bonutti (Figures 1-3 show a body having a lumen, and a first needle guide channel, capable of having a needle/suture backloaded therein, as set forth by Applicant)

U.S. Patent No. 6,159,234 to Bonutti et al. (Fig. 21 shows a body having a lumen, and a first needle guide channel, capable of having a needle/suture backloaded therein, as set forth by Applicant)

U.S. Patent No. 6,368,343 to Bonutti et al. (Fig. 5 shows a body having a lumen, and a first needle guide channel, capable of having a needle/suture backloaded therein, as set forth by Applicant)

U.S. Patent No. 6,451,031 to Kontos (Fig. 2 shows a body having a lumen, and a first needle guide channel, capable of having a needle/suture backloaded therein, as set forth by Applicant)

Response to Arguments

14. Applicant's arguments filed November 15, 2004 have been fully considered but they are not persuasive. Applicant argues that Whitin does not disclose every feature of the claimed invention, as amended. Examiner disagrees. Applicant seems to be arguing that Whitin does not disclose "backloading" a needle into a needle guide channel. Examiner agrees that Applicant specifically defines this terminology in the specification, but Examiner contends that Applicant is claiming a product of manufacture, not a method of performing surgery: thus, Whitin's invention need only be capable of such an intended use. Whitin shows in Fig. 9 (very clearly) needles (70), each in a separate needle guide channel (80). The needles are attached to sutures [Column 4, lines 18-19: "needles which carry suture ends"] and are used to drive the sutures through tissue. Each needle is *definitely capable* of being "positioned in the needle guide channel such that it will be advanced, sharp end first, out of the needle guide channel by the suture when an end of the suture is pulled": *Were a user to pull on one of the suture threads shown in Fig. 9, the respective needle would come out of the hole.* Regarding Claim 31, if a user pulls one of the suture threads of Fig. 9 in a proximal direction, the needle will be advanced distally (in the direction of needle guide channel (80)).

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15. Examiner recommends that Applicant claim a cylindrical body, a needle/suture, a needle guide channel *extending in the shape of an arc starting and finishing on the sidewall of the body*, and a separate lumen extending through the center of the body, in addition to other *structural details* that will set the claimed invention apart from the *plethora of art* that currently reads on the currently amended claims. There is no end of art that has two different lumens and has the capability of having a suture and needle extended through one of the lumens.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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December 20, 2004


ANH TUAN T. NGUYEN
PRIMARY EXAMINER

12/24/04